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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,202

07/25/2007

Larry R. Rohrschneider

FHCC:016US/ 10611971

5927

32425 7590 12/31/2009
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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

12/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,202	Applicant(s) ROHRSCHEIDER, LARRY R.	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-12,15-23,29-35,37,39,40,45-48 and 50-56 is/are pending in the application.
- 4a) Of the above claim(s) 40,45-48 and 50-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-12,15-23,29-35,37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 3, 5, 13, 14, 24-28, 36, 38, 41-44, 49, 57-76 have been canceled.

Claims 1, 4, 6-12, 15-23, 29-35, 37, 39, 40, 45-48, 50-56 remain pending.

Election/Restrictions

This application contains claims 40, 45-48 and 50-56 drawn to an invention nonelected with traverse in the reply filed on 4-17-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants' election of the 11.5 kb GFP construct species is acknowledged. The 11.5 kb fragment is nucleotides 49485-61006 of SEQ ID NO: 1 (pg 3, line 33). Applicants traverse the rejection because the other species are contained within the same upstream sequence and overlap with one another. Applicants' argument is not persuasive. The 11.5 kb construct cannot be searched as a whole, so fragments of it must be searched individually. In this case, nucleotides 49485-49985 of SEQ ID NO: 1, nucleotides 55668-55810 of SEQ ID NO: 1, and nucleotides 60506-61006 of SEQ ID NO: 1 were searched to establish whether the entire 11.5 kb fragment of SEQ ID NO: 1 from 49485-61006 (pg 3, line 33) was known in the prior art. The search of the three fragments listed above did not require a search of the smaller regions contained within the 11.5 kb fragment now claimed. It is noted that the species claimed have a common element – the smallest fragment disclosed (143 nucleotides of 55668-55810 of SEQ ID NO: 1) was common to all the fragments claimed. However, the search required for elected species does not require a search for the other species claimed; therefore, the

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species remain materially distinct and separate. It is noted that a search of the species encompassed by the claims as now amended is even greater as they encompass any 200 base pairs of SEQ ID NO: 1-5, which have no common element. Accordingly, the species election has been maintained.

Claims 1, 4, 6-12, 15-23, 29-35, 37 and 39 are under consideration as they relate to the 11.5 kb fragment, i.e. nucleotides 49485-61006 of SEQ ID NO: 1 (pg 3, line 33).

Applicant's arguments filed 9-18-09 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The title will have to be changed to more closely reflect the subject matter being examined.

Claim Rejections - 35 USC § 112

Claims 1, 4, 6-12, 15-23, 29-35, 37, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is being examined as it relates to an isolated polynucleotide comprising an s-ship promoter capable of promoting transcription operably connected to a

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heterologous nucleic acid sequence, wherein the polynucleotide comprises nucleotides 49485-61006 of SEQ ID NO: 1 (the 11.5 kb fragment elected).

Claim 15 is being examined as it relates to a nucleic acid comprising a promoter operably attached to a nucleic acid sequence from an s-ship gene or a portion thereof and a marker sequence, wherein the s-ship gene is disrupted by the marker sequence, and wherein the polynucleotide comprises nucleotides 49485-61006 of SEQ ID NO: 1 (the 11.5 kb fragment elected).

Claim 19 is being examined as it relates to an expression cassette comprising an s-ship promoter operably connected to a heterologous nucleic acid segment, wherein the expression cassette comprises nucleotides 49485-61006 of SEQ ID NO: 1 (the 11.5 kb fragment elected).

Claim 29 is being examined as it relates to a vector comprising an s-ship promoter, wherein the vector comprises nucleotides 49485-61006 of SEQ ID NO: 1 (the 11.5 kb fragment elected).

The 11.5 kb fragment is nucleotides 49485-61006 of SEQ ID NO: 1 (pg 3, line 33). Pg 4, line 15, states SEQ ID NO: 5 is the mouse s-ship promoter region in the 11.5 kb GFP construct. However, SEQ ID NO: 5 is 11.5 kb. Clarification is required.

The specification states the 11.5 kb GFP construct was made from two separate plasmids containing the two halves of the proposed s-ship promoter region (pg 70, line 15). The 11.5 kb GFP construct was used to make transgenic mice (pg 71, line 15). GFP expression was analyzed in embryos (pg 71, line 27). However, the specification does not provide adequate guidance for those of skill to make the 11.5 kb GFP

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construct by teaching the “two halves”, “the proposed s-ship promoter region” or the other elements other than a nucleic acid sequence encoding GFP. Fig. 3 shows a vague diagram of the construct but it does not teach the promoter used. Furthermore, applicants fail to teach how to interpret the expression of GFP in embryos. Accordingly, applicants do not enable those of skill to make or use the 11.5 kb fragment of nucleotides 49485-61006 of SEQ ID NO: 1 (SEQ ID NO: 5).

Response to Arguments

Applicants argue those of skill could have the 11.5 kb fragment produced in a lab, which would not constitute undue experimentation. Applicants’ argument is not persuasive. The Patent office is not aware of any company that would produce an 11.5 kb fragment. The 11.5 kb fragment of nucleotides 49485-61006 of SEQ ID NO: 1 (SEQ ID NO: 5) was made by applicants by piecing various sequences together, but applicants have failed to teach the elements that make up the 11.5 kb fragment. The purpose of issuing a patent is to protect applicants for an invention; in return applicants must provide adequate guidance for those of skill to make the invention once the patent term expires. In this case, merely providing the sequence is not an enabling disclosure because the burden required to have a company make the 11.5 kb fragment would be undue experimentation. Furthermore, the lack of disclosure in this regard at least prevents the those of skill as well as the patent office from searching the elements used to make the 11.5 kb fragment of nucleotides 49485-61006 of SEQ ID NO: 1 (SEQ ID NO: 5). This is also considered undue experimentation. As such, the enablement rejection has been maintained.

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Applicants argue the specification provides an example of making the 11.5 kb fragment on pg 70, lines 15-31. Applicants' argument is not persuasive. The citation discusses how to make a construct encoding GFP operably linked to the 11.5 kb fragment (11.5 kb-GFP construct). It does not teach how to make the 11.5 kb fragment used in the construct.

The elected species, the 11.5 kb fragment of SEQ ID NO: 1 from 49485-61006, remains free of the prior art because the three fragments of the 11.5 kb fragment searched did not have one reference in common. If applicants show each element was known in the art, an art rejection may result.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Krystal (US Patent 6,218,162), SEQ ID NO: 1, starting at nucleotide 800, begins with nucleotides 55668-55810 of SEQ ID NO: 1.

Lucas (Blood, 1999, Vol. 93, No. 6, pg 1922-1933) also taught nucleotides 55668-55810 of SEQ ID NO: 1.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner